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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|----------------------------|------------------|
| 10/768,229 | 01/30/2004 | Russel Miles Pinnisch | 1781 | 6209 |
| 27310 | 7590 | 09/03/2004 | | |
| PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131 | | | EXAMINER KRUSE, DAVID H | |
| | | | ART UNIT 1638 | PAPER NUMBER |

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/768,229 | PINNISCH ET AL. | |
| | Examiner | Art Unit | |
| | David H Kruse | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5, 8-12, 14-21, 23, 27 and 28 is/are allowed.
- 6) ☒ Claim(s) 24,25,29 and 30 is/are rejected.
- 7) ☒ Claim(s) 1,6,7,13,22 and 26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/30/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 30 April 2004 has been considered, a signed copy is attached hereto. The listed US Patent Applications will not be published on the face of the patent.

Specification

2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. See page 36, line 29; page 37, lines 12 and 30; page 38, lines 26 and 27; page 45, line 19; page 48, line 1.

Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). If the material is not considered by Applicant to be essential material, a statement on the record would obviate this objection (See MPEP 608.01(p)(I)).

Claim Objections

3. Claims 1, 6, 7, 13, 22 and 26 are objected to because of the following informalities:

Claim 1 should read -- A seed of -- because a claim should be directed to a single invention, and the claim as presently worded may unduly limit Applicant's invention.

At claim 6, line 1, "are from" should read -- are produced from -- to be consistent with claim 4.

At claim 7, line 2, "of inbred line" should read -- of maize inbred line -- for consistency with claim 1.

At claims 13 and 26, line 2, "of:" should read -- of -- as a matter of form.

Claim 22 should read -- A maize plant having modified fatty acid metabolism or modified carbohydrate metabolism produced by the method of claim 21. -- to clearly indicate what is claimed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 24, 25, 29 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because at step (a) Applicant claims crossing "PHB6R plants" with "plants of another maize line" that comprise a desired trait selected from a group of traits wherein it is unclear if the "plants of another maize line" comprise individuals with different traits, hence the metes and bounds of the invention is unclear.

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It is suggested that the claim be directed to crossing -- a PHB6R plant -- with -- a plant of another maize line --. Claim 25 is also indefinite because it does not obviate the indefiniteness of claim 24. Claims 29 and 30 are also indefinite for the same reason as that of claim 24.

Claim 29 is indefinite because at lines 5-6, the limitation "or inhibiting a polypeptide" is a function that cannot be performed by "a nucleic acid molecule" as claimed. The specification teaches transforming a plant with an antisense gene of stearoyl-ACP desaturase to increase stearic acid content (paragraph spanning pages 38-39). Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 29 and 30 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method comprising using another maize plant comprising a nucleic acid encoding a polypeptide selected from the group consisting of phytase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch branching enzyme or encoding an antisense gene of stearoyl-ACP desaturase, does not reasonably provide enablement for a method comprising another maize plant comprising a nucleic acid encoding stearyl-ACP desaturase or inhibiting a polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches transforming a plant with an antisense gene of stearyl-ACP desaturase to increase stearic acid content (paragraph spanning pages 38-39). The specification also teaches transforming a plant with a transgene encoding a phytase, a fructosyltransferase, a levansucrase, an alpha-amylase, an invertase and a starch branching enzyme (pages 39-40).

Applicant does not teach methods using maize plants comprising a nucleic acid that inhibits a polypeptide that modifies fatty acid metabolism, phytic acid metabolism or carbohydrate metabolism as claimed. The discrepancy as to the use of "stearyl-ACP desaturase" in the specification at page 38, line, 31, and "stearyl-ACP desaturase" at claim 29 should also be addressed in response to this Office action, and appropriate correction made.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides no guidance for maize plants comprising a nucleic acid that inhibits a polypeptide selected from the group consisting of phytase, stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch

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branching enzyme. Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to identify such maize plants.

Conclusion

8. The claims are free of the prior art, which neither teaches nor suggests inbred maize plant PHB6R, or methods of using it.
9. Claims 1, 6, 7, 13, 22 and 26 are objected to.
10. Claims 24, 25, 29 and 30 are rejected.
11. Claims 2-5, 8-12, 14-21, 23, 27 and 28 are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER
11 1638

David H. Kruse, Ph.D.
1 September 2004

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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.